# BILAG BR Site File

**IRAS ID: 24407**

**Short Title: BILAG Biologics Prospective Cohort**

**Date completed: 26/03/2024**

| *Document Description (eg Protocol, Consent Form, MHRA CTA, Agreement template, etc)* | *File Name* | *Version* | *Version Date* |
| --- | --- | --- | --- |
| Protocol | BILAG BR protocol | 3.1 | 01/03/2024 |
| Information sheet | BILAG BR PIS - ADULTS | 7.0 | 19/03/2021 |
| Information sheet | Patient information Sheet – parents | 5 | 19/03/2021 |
| Information sheet | Patient information Sheet – children | 4 | 11/03/2011 |
| Consent form | BILAG BR CONSENT FORM - ADULTS | 7.0 | 13/07/2021 |
| Consent form | Consent form – parents | 5 | 13/07/2021 |
| Assent form | Assent Form – children and young people | 4 | 22/07/2011 |
| Invitation letter | Invitation-Letter\_V1\_10/07/2015 | 1 | 10/07/2015 |
| GP letter | GP letter\_Version1\_16092009 | 1 | 16/09/2009 |
| Registration form | Consultant Registration form | 5.0 | 21/11/2018 |
| Participant diary |  |  |  |
| Baseline registration questionnaire | Consultant baseline | 6.0 | 13/01/2021 |
| Follow-up questionnaire | Consultant Follow-up Questionnaire | 5.1 | 03/02/2021 |
| BILAG 2004 Index |  |  | 01/09/2009 |
| SLEDAI 2K |  |  |  |
| SLICC Damage Index |  |  |  |
| Event of special interest pack (serious adverse event validation questionnaires) | ESI pack October 2013 | 1 | 10/10/2013 |
| Switcher form | Control to biologic switch form version 1.2 12092013 | 1.2 | 12/09/2013 |
| Retreatment form | Retreatment or biologic switch form version 1.2 10102013 | 1.2 | 10/10/2013 |
| Blood sample admin form | BILAG BR Sample collection form v2.1 18112021 | 2.1 | 18/11/2021 |
| Blood sample collection letter |  | 1.0 | 23/03/2018 |
| Promotional poster | Clinic Poster v1 16/09/2009 | 1 | 16/09/2009 |
| Eligibility for Rituximab | Rituximab funding patient eligibility v1.0 17092013 | 1 | 17/09/2013 |
| Lifestyle Questionnaire | BILAG BR lifestyle questionnaire v 1 29092009 | 1 | 29/09/2009 |
| LupusQoL | BILAG BR LupusQoL | 3 | 26/05/05 |
| EQ5D | BILAG BR EQ5D European Quality of Life Questionnaire |  |  |
| SF36 | SF\_36 |  |  |
| CHAQ Form |  |  |  |
| CHQ Form |  |  |  |
| CHAQ Adolescent Form |  |  |  |
| CHU-9D form | CHU9D\_v1\_18012008 | 1 | 18/01/2008 |
| Patient diary | BILAG BR Patient diary | 1 | 24/09/2009 |
| Supplementary PIS – renal blocks | BILAG BR supplementary PIS – renal tissue adults | 2.0 | 21/11/2018 |
| Supplementary consent form – renal blocks | Supplementary consent form – renal tissue adults | 2.0 | 21/11/2018 |
| Covering letter – renal blocks | Covering letter – retrospective recovery of renal blocks | 1.0 | 23/03/2018 |
| Transparency Information Sheet | IRAS ID 24407 - BILAG BR Transparency Information Sheet v1. 24.05.18 | 1.0 | 24/05/18 |
| Supplementary PIS – Covid 19 | BILAG BR Supplementary PIS – Covid 19 v1.2 30092021 | 1.2 | 30/09/2021 |
| Supplementary consent form – Covid 19 | Lupus\_and\_Covid-19 supplementary consent form (paper form) 29092021 | 1.2 | 29/09/2021 |
| Instructions for Dry Blood Spot Collection | BILAG BR Instructions for Dry Blood Spot Collection version 2.1 30092021 | 2.1 | 30/09/2021 |
| Lupus and Covid-19 Survey | Lupus\_and\_Covid-19 Survey version 1.3 (paper form) 05112021\_ | 1.2 | 23/09/2021 |

Please add rows as necessary